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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,530	10/10/2001	Jon G. Wilkes	4239-60896	9402
36218	7590	04/28/2004		
KLARQUIST SPARKMAN, LLP 121 S.W. SALMON STREET, SUITE #1600 ONE WORLD TRADE CENTER PORTLAND, OR 97204-2988			EXAMINER LY, CHEYNE D	
			ART UNIT 1631	PAPER NUMBER
DATE MAILED: 04/28/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/975,530

Applicant(s)

WILKES ET AL.

Examiner

Cheyne D Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-32 and 67-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20, 21, 23-30, 32, 67, 68, and 70 is/are rejected.
- 7) ☒ Claim(s) 22, 31, 69 and 71 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>March 04, 2004</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' arguments filed March 15, 2004 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.
3. Applicant's Interview Summary, page 6, Item 2, filed March 15, 2004, has been accepted.
4. The After Final amendment, filed March 15, 2004, has been entered.
5. The Species Election Requirement, mailed February 27, 2003, has been withdrawn.
6. Claims 20-32 and 67-71 are examined on the merits.

OBJECTIONS

7. Claims 22, 31, 69, and 71 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

CLAIM REJECTIONS - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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9. Claims 20, 21, 23, 25-28, 30, 67, 68, and 70 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Acheson et al. (1993).

RESPONSE TO ARGUMENT

10. Applicant's argument directed to references Goodacre et al. and Sockalingum et al. has been found to be persuasive and said argument has been responded to with the instant prior art rejection below.

11. Acheson et al. discloses a method for comparing the expression level of SLT-I B-subunit (fingerprint spectra) from microorganisms *V. cholerae* (first microorganism) to *E. coli* (second microorganism) grown in the presence (first environmental factor effecting the metabolic state) or absence (second environmental factor effecting the metabolic state) of IPTG (Abstract etc.). It is noted that microorganisms of similar class and genus cited above are metabolically similar, and *E. coli* and *V. cholerae* are of different species, as in instant claims 26-28 and 30.

12. *V. cholerae* and *E. coli* are grown in cultures present of IPTG (first environmental factor) (page 1099, column 2, to page 1100, Culture conditions and SLT-I B-subunit preparation §), as in instant claim 20, lines 4-5.

13. The concentration of SLT-I B-subunit protein (fingerprint spectra) from *E. coli* and *V. cholerae* cultured under the first environmental factor is summarized in Tables 1 and 2, as in instant claim 20, lines 6-8.

14. The concentration of SLT-I B-subunit protein (fingerprint spectra) from *E. coli* cultured in the absence of IPTG (second environmental factor) is summarized in Tables 1 and 2 (page 1102), as in instant claim 20, lines 9-11.

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15. Figure 3, Table 1, and Table 2 illustrate the derived relationship of *E. coli* (second microorganism) being cultured under the first and second environmental factors (page 1101), as in instant claim 20, lines 12-14.

16. Acheson et al. reasons that expression of SLT-I B subunit from *V. cholerae* might be constitutive (expectation) as demonstrated in *E. coli* TB1 and wishes (expectation) to investigate whether this would be true as well for the B subunit of SLT-I (page 1103, column 2, lines 41-51).

17. With the expectation of SLT-I B subunit being constitutive expressed in *V. cholerae* above, Acheson et al. applies the derived relationship from the *E. coli* (second organism) by changing (transform) the culturing conditions of *V. cholerae* (first organism) in the presence of IPTG (first environmental factor) to the absence of IPTG (second environmental factor) for constitutive expression (page 1099, column 2, to page 1100, Culture conditions and SLT-I B-subunit preparation §, and Tables 1-2). *V. cholerae* cultured in the absence of IPTG results in a higher concentration (compensating) of SLT-I B-subunit due to SLT-I B-subunit being constitutively expressed as expected (page 1103, column 2, lines 47-50, Figure 4, and Tables 1 and 2), as in instant claim 20, lines 15-19, claim 23, and claim 25.

18. The method of Acheson et al. comprises culturing microorganisms in 5 ml of LB medium, then, the cultures are divided in half (batch), and IPTG is added to one of the cultures (library) (page 1099, column 2, to page 1100, Culture conditions and SLT-I B-subunit preparation §), as in instant claims 21, 67, and 68.

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19. Acheson et al. discloses the submission of the expected fingerprint spectrum of V. cholerae into Tables 1 and 2 (database) wherein the data in the related tables are classified by organism names (keys) (page 1102, Tables 1 and 2), as in instant claim 70.

CLAIM REJECTIONS - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

22. Claims 20, 21, 23-30, 32, 67, 68, and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acheson et al. (1993) taken with Jeng et al. (US006087182A).

23. Acheson et al. discloses the limitations to claim 20, 21, 23, 25-28, 30, 67, 68, and 70 as discussed above.

24. However, Acheson et al. does not disclose the limitations to claims 24, 29, and 32.

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25. Jeng et al. discloses a method for improving the accuracy of measurement of parameters of analytes such as protein in biological samples (Abstract etc.). The improvement of Jeng et al. is directly applicable to the measurement of the SLT-I B-subunit protein expression of Acheson et al.

26. Jeng et al. discloses Principle Component Analysis and Neural Networks as a type of tools useful in improving the accuracy of measurement of parameters of analytes such as protein in biological samples (column 28, lines 57-59), as in instant claims 24 and 29.

27. Jeng et al. discloses the limitations of the computer must be considered in the method of improving the accuracy of measurement of parameters of analytes such as protein in biological samples (column 25, lines 57-60), as in instant claim 32.

28. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated by the improvement of Jeng et al. cited above and utilize said improvement to increase the accuracy of measuring the SLT-I B-subunit protein (biological fingerprint spectra) as taught by Acheson et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use the method of Jeng et al. to measure the amount of the SLT-I B-subunit protein expression accurately as taught by Jeng et al. and Acheson et al.

CONCLUSION

29. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61

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(November 16, 193), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 872-9306.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

31. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

32. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

C. Dune Ly
4/21/04

Ardin H. Marschel 4/26/04
ARDIN H. MARSCHEL
PRIMARY EXAMINER